

**Center for Regulatory Effectiveness' ("CRE") Comments on  
EPA Proposed Revised Method for National Level  
Endangered Species Risk Assessment Process for  
Biological Evaluations of Pesticides ("proposed ESA  
Risk Assessment Procedures").  
Comments Submitted at [www.regulations.gov](http://www.regulations.gov),  
Docket ID EPA-HQ-OPP-2019-0185**

## **INTRODUCTION**

We first discuss two recent Office of Management and Budget ("OMB") Memoranda that have a significant impact on EPA's proposed ESA Risk Assessment Procedures. We next exhort EPA to heed Congress' intent and requirements in the Farm Bill. There Congress required that EPA and the Services craft a pesticide ESA consultation process that is affordable and practicable as well as protective.

## **OMB MEMORANDUM ON CRA COMPLIANCE**

The first OMB Memorandum is "Guidance on Compliance with the Congressional Review Act."<sup>1</sup>

This OMB Memorandum explains that EPA has to submit its proposed ESA Risk Assessment Procedures to OMB so that OMB can determine whether the new procedures are "Major Rules" under the CRA. EPA has to include an economic analysis in its package sent for OMB CRA review.<sup>2</sup>

EPA's new procedures are "Major Rules" subject to the CRA.

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<sup>1</sup> *Guidance on Compliance with the Congressional Review Act* (OMB April 11, 2019), at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf>

<sup>2</sup> *Id.*, pages 4-7.

EPA's proposed ESA Risk Assessment Procedures are "rules" because they are *"the organization, procedure or practice requirements of an agency" AND/OR "guidance documents [and] general statements of policy."*<sup>3</sup> Consequently, They are rules under the CRA, even if EPA argues that they are only "guidance documents."<sup>4</sup>

They are also MAJOR rules under the CRA because they are likely to result in

- "(A) an annual effect on the economy of \$100,000,000 or more;*
- (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or*
- (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets."*<sup>5</sup>

EPA intends to use its proposed ESA Risk Assessment Procedures during pesticide FIFRA registrations and ESA consultations. In previous comments, CRE used USDA economic impact estimates to discuss the extreme effects that pesticide FIFRA risk assessments and ESA consultation risk assessments can have. These impacts are well over \$100,000,000.00, especially when one considers the many pesticides subject to them.<sup>6</sup> EPA's proposed ESA Risk Assessment Procedures could preclude use of a pesticide, thereby causing a major increase in costs or prices for consumers *etc....*

Even if EPA disagrees with us about the Procedures' Major Rule status, the OMB CRA Memo still requires that EPA submit for OMB's determination whether EPA's proposed ESA Risk Assessment

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<sup>3</sup> *Id.* pages 2-3.

<sup>4</sup> See *id.* page 3.

<sup>5</sup> See *id.* pages 3-4.

<sup>6</sup> See CRE's Comments on Endangered Species Act ("ESA") Section 7 Consultations pages 3-5 at <http://www.thecre.com/creipd/wp-content/uploads/2017/08/21august2sapestfinal.pdf> .

Procedures are Major Rules BEFORE EPA implements the Procedures. Once again, EPA's OMB submission has to include EPA's economic analysis.<sup>7</sup>

The OMB CRA memo also reminds agencies that

“Any information that the agency relies upon for its analysis should comply with the Information Quality Act (IQA), OMB's information quality guidance, and the agency's supplemental IQA guidance.”

Which brings us to our second comment: EPA's proposed ESA Risk Assessment Procedures also have to comply with EPA's new Memorandum on Information Quality Act (“IQA”) Guidelines.

## **OMB MEMORANDUM ON IQA IMPLEMENTATION**

This OMB Memorandum is entitled “Improving Implementation of the Information Quality Act.”<sup>8</sup>

Its stated purpose “is to reinforce, clarify, and interpret agency responsibilities with regard to responsibilities under the Information Quality Act (IQA).”<sup>9</sup>

EPA's proposed ESA Risk Assessment Procedures are subject to the IQA as interpreted by this OMB Memorandum. Federal agencies including EPA have to amend their IQA Guidelines to be consistent with this OMB Memorandum by July 23, 2019.

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<sup>7</sup> *Guidance on Compliance with the Congressional Review Act* (OMB April 11, 2019), pages 4-7 at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf>.

<sup>8</sup> *Improving Implementation of the Information Quality Act* (OMB April 24, 2019), at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

<sup>9</sup> *Id.* page 1 at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

We stress the following four points about this OMB's Memorandum effect on EPA's proposed ESA Risk Assessment Procedures.

***First Point: EPA's Proposed ESA Risk Assessment Procedures are Influential Information Required to Comply with the OMB IQA Memorandum***

The OMB IQA Memorandum emphasizes new IQA requirements for "influential information." The OMB IQA Memorandum explains that

"The [IQA] Guidelines characterize a subset of agency information as 'influential scientific, financial, or statistical information' that is held to higher quality standards. This is scientific, financial, or statistical information that 'the agency can reasonably determine ... will have or does have a clear and substantial impact on important public policies or important private sector decisions.'"<sup>10</sup>

EPA's Proposed ESA Risk Assessment Procedures are clearly "influential information" under this definition. EPA is proposing them in partial response to a statutory mandate in the Farm Bill. They will significantly affect ESA pesticide consultations between EPA and the Services. They will significantly affect pesticide use and availability. They will have a significant economic effect on pesticide production and agriculture.

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<sup>10</sup> *Id.* page 3 at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

***Second Point: EPA has to Provide Increased Access to Data as part of the Proposed ESA Risk Assessment Procedures***

OMB's Government-wide 2002 IQA Guidelines require that influential analyses must be disseminated with sufficient details to allow third-party reproduction, and they must be disseminated with specific details on the uses and limitations of data sets. OMB's 2019 IQA Memorandum directs agencies to provide wider access to data, models and analyses used for influential information, as well as any specialized computer code used, if consistent with applicable law and policy. Additionally, agencies should provide the underlying assumptions, uncertainties and probabilities associated with influential information.<sup>11</sup>

***Third Point: Expanded and Mandatory Peer Review of the Proposed ESA Risk Assessment Procedures***

The OMB IQA Memorandum instructs agencies to ensure compliance with the OMB's Final Information Quality Bulletin for Peer Review, issued in 2004.<sup>12</sup> Compliance with the Bulletin was already required under the Information Quality Act, but OMB states in the Memorandum that "only some agencies have robust peer review mechanisms." Agencies have existing obligations to conduct peer review of influential scientific information and send annual reports of completed peer reviews to OMB. The IQA Memorandum instructs agencies to increase reviewers' focus on objectivity of data and requires a second round of peer review if there are substantial changes based on the first.<sup>13</sup>

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<sup>11</sup> *Id.* pages 7-9 at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

<sup>12</sup> OMB's Peer Review Bulletin is available at [https://www.cio.noaa.gov/services\\_programs/pdfs/OMB Peer Review Bulletin m05-03.pdf](https://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf).

<sup>13</sup> *Improving Implementation of the Information Quality Act (OMB April 24, 2019)* page 4 at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

EPA's proposed ESA Risk Assessment Procedures have never been peer reviewed in accordance with OMB's Peer Review Bulletin. Most of the Procedures have never been peer reviewed at all.

***Fourth Point: OMB Has to Review and Approve  
EPA's Responses to any IQA Requests for Correction ("RFC") of the  
ESA Risk Assessment Procedures***

The OMB IQA Memorandum states:

"Agencies should share draft responses to RFCs and appeals with OMB prior to release to the requestor for assessment of compliance with the above norms."<sup>14</sup>

The OMB IQA Memorandum also explains how EPA is to process and consider IQA Requests for Correction.<sup>15</sup>

**CONGRESS EXPECTS EPA AND THE SERVICES TO DEVELOP  
PRACTICABLE AND EFFECTIVE  
PESTICIDE CONSULTATION PROCEDURES**

As our final comment, we note that EPA's proposed ESA Risk Assessment Procedures are a partial and essential response to the Farm Bill's pesticide ESA consultation requirements.<sup>16</sup> The Farm Bill's requirements clearly evince congressional intent that EPA and the Services, with the Department of Agriculture and stakeholder help, develop a pesticide ESA consultation process that works.

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<sup>14</sup> *Id.* page 10, at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

<sup>15</sup> *Id.* pages 9-11, at <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>.

<sup>16</sup> The Farm Bill's inter-agency pesticide ESA consultation requirements are at <http://www.thecre.com/forum1/?p=42164>.

Everyone knows that the current and past consultations are not practicable, are too expensive, and are too time and resource consuming. They often produce inaccurate risk assessments that grossly over state risk, and they often have nothing to do with real world conditions.

In order to implement congressional intent, EPA and the Services must be willing to depart from the NASEM recommendations when they prove impracticable.<sup>17</sup> Nothing in the NASEM report binds EPA.

By contrast, in order to implement congressional intent, EPA will have to comply with OMB's CRA Memorandum and with OMB's IQA Memorandum.

We look forward to working with EPA and the Services in developing pesticide risk assessment and other ESA consultation procedures that actually work; that are both protective and sustainable.

Thank you for this opportunity to comment.

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The Center for Regulatory Effectiveness  
[www.TheCRE.com](http://www.TheCRE.com)

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<sup>17</sup> The NASEM pesticide ESA consultation report is available at <https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides>.